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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,713	10/25/2006	Charli Kruse	B1180/20064	3221
3000 7590 07/21/2010 CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOV, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212				
EXAMINER SCHULTZ, JAMES				
ART UNIT 1633		PAPER NUMBER		
NOTIFICATION DATE 07/21/2010		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

### Office Action Summary

**Application No.**

10/599,713

**Applicant(s)**

KRUSE ET AL.

**Examiner**

JD SCHULTZ, PhD

**Art Unit**

1633

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 2, 6, 12, 15, 16, 21, 25-28, 30, 34 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 7-11, 13, 14, 17-20, 22-24, 29, 31-33 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on originally is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See action
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

The examiner assigned to your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to James (Doug) Schultz, Primary Examiner, Art Unit 1633.

### ***Election/Restrictions***

Applicant's election without traverse of group II, claims 1, 3-5, 7-11, 13-24, and 28-35, and species drawn to "muscle cells" in Group A, "dead cells" in Group B and "non-human mammal cells" in Group C in the reply filed on April 1, 2010 is acknowledged.

Claims 2, 6, 12, 25-27, and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Furthermore, claims 15, 16, 21, 28, 30, and 34 are also withdrawn as being directed to non-elected species. Election was made **without** traverse in the reply filed on April 1, 2010.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 12/5/2006 was filed before the mailing date of the instant first action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner, and a signed and initialed copy is enclosed herewith.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 3-5, 7-11, 13, 14, 17-19, 22-24, 29, 31-33, and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by U. S. Patent Application Publication Number 2006/0121006 (Chancellor et al.).

The instant invention embraces a method for producing biological material for use as feed comprising aggregating stem cells from differentiated exocrine glandular tissue to form organoid bodies followed by preparation of the composition from the organoid bodies (claim 1). The invention also embraces aggregating the stem cells in the culture medium containing at least one additive that influences differentiation of stem cells (claim 3) or tissue bodies (claim 29), or wherein the preparation of the composition is formed from a secondary organoid body (claim 4), or wherein the preparation comprises growing the organoid bodies to form tissue bodies (claim 5), or wherein the secondary organoid bodies are cultured with at least one additive to obtain a certain cell type (claim 7), which embraces muscle cells (claim 8), or wherein differentiation is influenced by in addition of differentiated cells (claim 9), which may be autologous cells (claim

10). The organoid or tissue bodies may be in a dead state during the preparation of the material composition (claims 12 and 31 respectively).

Preparation may involve combining organoid bodies to form a composite (claims 13 and 33 respectively), or wherein the organoid (claim 14) or tissue bodies (claim 33) are subjected to at least one of the following steps: A) growing together, B) mutual inherent adhesion, C) compression, or D) loading onto or into a carrier device. The composite may be adjusted during the preparation by the form of an imprinting device (claim 17), which may be a cultivating substrate, an imprinting surface, or a flexible container (claim 18). An inner structure of the material composition of claim 1 may be adjusted during preparation (claim 19).

Flavoring substances may be added (claim 22). The stem cells may be isolated from glandular tissue of a vertebrate (claim 23), which embraces glandular tissue from nonhuman mammals (claim 24). Preparation of the material composition may comprise combining tissue bodies to form a composite (claim 32), which may be adjusted during the preparation by its growth (claim 35).

Chancellor et al. teach a method for producing biological material for use as feed comprising isolating and expanding stem cells in culture followed by preparation of the composition for consumption by humans or other organisms (abstract, or paragraph 0004 for example). Chancellor et al. teaches that such stem cells may be isolated from liver, which is considered an exocrine gland (paragraphs 0031 for example). Chancellor et al. also teaches growing stem cells into tissues, and therefore considered to teach primary organoids and secondary organoids forming into tissue bodies. Chancellor et al. teaches culturing the stem cells in vivo to influence the differentiation of cells, and particularly contemplate a developmental

lineage directed to making muscular tissue. Chancellor et al. also contemplates the production and packaging of the resultant food products, including compressing the developed tissue, as well as providing for the growth of such tissue on substrates (which may be considered carrier devices) and adding flavoring. The claims are thus considered anticipated.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5, 7-11, 13, 14, 17-20, 22-24, 29, 31-33, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Eelen et al. (WO 99/31223), in view of Kruse et al. (Appl. Phys. A, 2004. 79:1617-1624, applicants IDS) and Simpson et al. (U. S. Patent Application Publication Number 2004/0037813).

The instant invention embraces a method for producing biological material for use as feed comprising aggregating stem cells from differentiated exocrine glandular tissue to form organoid bodies followed by preparation of the composition from the organoid bodies (claim 1). The invention also embraces aggregating the stem cells in the culture medium containing at least one additive that influences differentiation of stem cells (claim 3) or tissue bodies (claim 29), or wherein the preparation of the composition is formed from a secondary organoid body (claim 4), or wherein the preparation comprises growing the organoid bodies to form tissue bodies (claim 5), or wherein the secondary organoid bodies are cultured with at least one additive to obtain a

certain cell type (claim 7), which embraces muscle cells (claim 8), or wherein differentiation is influenced by in addition of differentiated cells (claim 9), which may be autologous cells (claim 10). The organoid or tissue bodies may be in a dead state during the preparation of the material composition (claims 12 and 31 respectively).

Preparation may involve combining organoid bodies to form a composite (claims 13 and 33 respectively), or wherein the organoid (claim 14) or tissue bodies (claim 33) are subjected to at least one of the following steps: A) growing together, B) mutual inherent adhesion, C) compression, or D) loading onto or into a carrier device. The composite may be adjusted during the preparation by the form of an imprinting device (claim 17), which may be a cultivating substrate, an imprinting surface, or a flexible container (claim 18). An inner structure of the material composition of claim 1 may be adjusted during preparation (claim 19), which may be by an effect of an electrical current (claim 20).

Flavoring substances may be added (claim 22). The stem cells may be isolated from glandular tissue of a vertebrate (claim 23), which embraces glandular tissue from nonhuman mammals (claim 24). Preparation of the material composition may comprise combining tissue bodies to form a composite (claim 32), which may be adjusted during the preparation by its growth (claim 35).

Van Eelen et al. teaches a method for producing nutritional meat in vitro, the method comprising selecting mammalian cells, seeding onto a substrate, growing into a monolayer supplemented with factors that influence development, and harvesting the cells to make an edible muscle tissue product. Van Eelen et al. is considered to necessarily teach their developing tissue

as passing through both primary and secondary organoid bodies, since the instant specification (at paragraph 0040) broadly defines both organoid bodies as that which develops from a culture adhesion monolayer for a period of time sufficient to cause differentiation into tissue, which is taught by Van Eelen et al. The monolayer is further treated by folding, mixing or shaping. Van Eelen et al. does not teach the method whereby the cells are derived from differentiated exocrine gland tissue to form organoid bodies, nor does Van Eelen et al. teach adjusting an inner structure by effect of an electrical current.

Kruse et al. teach that pancreatic stem cells (i.e. exocrine glandular stem cells) are particularly pluripotent and surprisingly viable.

Simpson et al. teach that electric current can be applied to differentiating stem cells to encourage a commitment to skeletal muscle lineage.

It would have been obvious to one of ordinary skill in the art to combine the method of differentiating hepatic derived stem cells as taught by Kruse et al. to differentiate pancreatic stem cells into a biological material to be used for food as taught by Van Eelen et al. teach that a variety of different stem cell types can be used for developing biological material as feed. One of ordinary skill in the art would have been motivated to do so, since Kruse et al. teach that these cells can differentiate into a large variety of cell types, and have surprising viability, and since . Furthermore, one of ordinary skill in the art would have been motivated to supply an electric current to cell cultures of these cells, since Simpson et al. teach the use of electric current to stimulate muscle differentiation from stem cells. Accordingly, in the lack of evidence to the contrary, the invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.



### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-5, 7-11, 13, 14, 17-20, 22-24, 29, 31-33, and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-27 of copending Application No. 12/162077, in view of Van Eelen et al. (WO 99/31223), in view of Kruse et al. (Appl. Phys. A, 2004. 79:1617-1624, applicants IDS) and Simpson et al. (U. S. Patent Application Publication Number 2004/0037813).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application teach making muscle cells from exocrine derived stem cells that are identical to those disclosed and claimed for use instantly.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-5, 7-11, 13, 14, 17-20, 22-24, 29, 31-33, and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-59 of copending Application No. 11/597317, in view of Van Eelen et al. (WO 99/31223), Kruse et al. (Appl. Phys. A, 2004. 79:1617-1624, applicants IDS) and Simpson et al. (U. S. Patent Application Publication Number 2004/0037813).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application teaches making muscle cells and three dimensional models culture systems thereof from exocrine derived stem cells that are identical to those disclosed and claimed for use instantly.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-5, 7-11, 13, 14, 17-20, 22-24, 29, 31-33, and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31-68 of copending Application No. 11/597317, in view of Van Eelen et al. (WO 99/31223), Kruse et al. (Appl. Phys. A, 2004. 79:1617-1624, applicants IDS) and Simpson et al. (U. S. Patent Application Publication Number 2004/0037813).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application teaches methods of testing substances

on stem cells that have been differentiated into muscle cells (among other cell types) using exocrine derived stem cells that are identical to those disclosed and claimed for use instantly.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-5, 7-11, 13, 14, 17-20, 22-24, 29, 31-33, and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-47 of copending Application No. 10/820430, in view of Van Eelen et al. (WO 99/31223), Kruse et al. (Appl. Phys. A, 2004. 79:1617-1624, applicants IDS) and Simpson et al. (U. S. Patent Application Publication Number 2004/0037813).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application teaches stem cells that have been differentiated into muscle cells that are identical to those disclosed and claimed for use instantly.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-5, 7-11, 13, 14, 17-20, 22-24, 29, 31-33, and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-28 of copending Application No. 10/561628, in view of Van Eelen et al. (WO 99/31223), Kruse et al. (Appl. Phys. A, 2004. 79:1617-1624, applicants IDS) and Simpson et al. (U. S. Patent Application Publication Number 2004/0037813).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application teaches stem cells that have been transfected to express pancreatic hormones, and that are capable of being used in the instant invention, and are identical to those disclosed and claimed for use instantly.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-5, 7-11, 13, 14, 17-20, 22-24, 29, 31-33, and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30-53 of copending Application No. 11/547678, in view of Van Eelen et al. (WO 99/31223), Kruse et al. (Appl. Phys. A, 2004. 79:1617-1624, applicants IDS) and Simpson et al. (U. S. Patent Application Publication Number 2004/0037813).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application teaches stem cells that are differentiated into an epithelial lineage, and that are thus capable of being used in the instant invention since the cells are identical to those disclosed and claimed for use instantly.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JD SCHULTZ, PhD whose telephone number is (571)272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James (Doug) Schultz, PhD/  
Primary Examiner, Art Unit 1633